REMARKS

I. Nationalization

This application represents the U.S. national stage under 35 U.S.C. § 371 of PCT Application Serial No. PCT/GB03/00062, filed January 10, 2003, which claims priority to PCT Application Serial No. PCT/US02/31944, filed September 24, 2002, and to U.S. Provisional Application No. 60/392,109, filed June 28, 2002, and to UK Application No. GB0200507.2, filed January 10, 2002.

Although the text of the International Application was presumably transmitted to the U.S. receiving office from the International Bureau, as a precaution under 35 U.S.C. § 371(c)(2), an additional copy is enclosed herewith in the form of published PCT Application No. WO 03/057235.

II. 30 Month Deadline

The 30 month deadline for national filing is July 10, 2004. As July 10, 2004 falls on a Saturday, the present U.S. application is timely filed on Monday, July 12, 2004, in accordance with 37 C.F.R. § 1.7.

III. Amendments to the Specification

Amendments to the specification are being made to revise the title, to perfect the claims for priority, to correct typographical errors in certain sequences and to insert the abstract. Pages with the correct U.S. sequence listing are also inserted by amendment (see below). No new matter is encompassed by the amendments to the specification. The amendments comply with the revisions to 37 C.F.R. § 1.121.

IV. National Stage Claims

After according a U.S. filing date, and **before** calculating the filing fee, entry of the foregoing claim amendments is respectfully requested.

As the claims in the PCT application were drafted in European style, including first and second medical use claims and multiply dependent claims, Applicants have revised the claims to better accord with U.S. practice, reduce the filing fee and to place the application in form for U.S. examination. Submission of the present claims does not represent abandonment of any of the subject matter of the claims in the PCT application.

The present claims are fully supported by the claims in the PCT application, as well as by the specification and claims of the PCT and priority applications, and the revised and new claims do not in any way constitute new matter.

V. Status of the Claims

Prior to entry into the national stage, claims 1-57 were pending. Presently, claims 1-27 and 30-57 have been amended without prejudice or disclaimer, to comply with U.S. requirements and to reflect certain embodiments of the invention. Claims 58-76 have been added, which are unified with claims 1-57 and supported by the specification and claims of the present and priority applications. No claims have been canceled.

Claims 1-76 are therefore in the case. According to the revisions to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

VI. Support for the Claims

The revisions to the claims are being made to better accord with U.S. practice, to reduce the filing fee and to reflect certain aspects of the invention in the PCT application. The present claims are fully supported by the specification and claims of the PCT and priority applications.

To reduce the filing fees by reducing the number of independent claims, claim 1 has been revised to include the features of claims 1, 2, 3, 4, 5 and 6, and is supported thereby. In addition, the phrase "increasing energy expenditure" has been added, which is supported by the specification at least at page 3, lines 19-22 and at page 23, lines 21-25.

Each of claims 2, 3, 7 and 8 has been revised to depend from claim 1, and are supported by claims 1-8.

Claims 4, 5 and 6 have been revised to recite the administration of PYY, GLP-1 and both PYY and GLP-1, respectively, without the agonist language. These claims are supported throughout the specification and PCT claims, including claim 1.

Claim 9 has been revised to recite only one of the original two embodiments, in better accordance with U.S. practice.

Claim 10 has been revised to be singly dependent and to better accord with claim 1.

Each of claims 11, 12 and 13 has been revised to be singly dependent.

In claim 14, intracistemal, intravaginal, intraperitoneal, oral, topical, transmucosal, and rectal administration and pulmonary inhalation have been added. These are supported throughout the specification, *e.g.*, at least at page 20, lines 11-15; page 27, lines 5-15; and at page 30, lines 1-3.

Claims 15 and 16 have been revised to be singly dependent and to better accord with claim 1.

Claim 17 has been revised to more simply recite administration at least 30 minutes prior to a meal, as supported throughout the specification, *e.g.*, at least at page 26, line 12.

Claim 18 has been revised to more simply recite administration in multiple or divided doses, as supported throughout the specification, *e.g.*, at least at page 26, lines 6-8 and at page 37, line 17.

Claims 19 and 20 have been revised to be singly dependent and to better accord with claim 1. Claim 20 has also been revised to recite effects over 24 hours, which is supported throughout the specification, *e.g.*, at least at page 39, lines 1-3.

Claims 21, 22, 23 and 24 have been revised to be singly dependent and to recite only one exemplary range, or only one exemplary dose, in better accordance with U.S. practice.

Claims 25, 26, 27, 30, 31, 32 and 33 have been revised to be singly dependent and to better accord with the claims from which they depend.

Claim 34 now recites substantially simultaneous administration, as supported by claim 9 and throughout the specification, *e.g.*, at least at page 3, lines 29-31.

Claims 35 and 36 have been revised to recite the administration of a PYY agonist and a GLP-1 agonist, respectively, which is supported throughout the specification and PCT claims, including claim 1.

Each of claims 37, 38, 39, 40, 41, 42 and 43 have been revised to recite an exemplary dose, as supported by claims 21, 22, 23 and 24.

Claims 44 and 45 have been revised to better accord with claim 1.

Each of claims 46, 47, 48, 49, 50, 51 and 52 has been revised to be singly dependent and to better accord with U.S. practice.

The second medical use format of claim 53 has been revised to become a U.S. treatment method claim, as supported by claims 53 and 1 to 8.

Dependent second medical use claims 54, 55, 56 and 57 have been converted to method claims and revised to better accord with U.S. practice.

Each of new claims 58, 59, 60, 61, 62, 63, 64 and 65 recite an exemplary dose, as supported by claims 21, 22, 23 and 24.

New claim 66 recites administration of PYY_{3-36}, as supported throughout the specification with an exemplary first reference at page 3, line 2.

New claims 67 and 68 recite administration in a pulse dose and as a slow, sustained or controlled release preparation or from a pump or implantable drug infusion device, respectively. These embodiments are supported throughout the specification, *e.g.*, at least at page 3, line 26; page 26, lines 15-21; and from page 30, line 30 to page 32, line 7.

Claim 70 recites administering the PYY or agonist at about 0.5 to about 135 pmol per kilogram body weight of the subject, as supported throughout the specification, *e.g.*, at least at page 26, lines 27-29.

New claim 71 represents the subject matter of former claim 18, and new claim 72 represents the subject matter of former claim 20.

Claims 73 and 74 recite administration of an additional appetite suppressant and a food intake-reducing agent, plasma glucose-lowering agent or plasma lipid-altering agent, respectively. These embodiments are supported throughout the specification, *e.g.*, at least at page 11, lines 1-4; page 33, lines 24-26; page 37, lines 1-5; and at page 27, lines 16-20.

Claim 75 is a separate independent claim based upon current claim 1 without the agonist language, which is supported throughout the specification and PCT claims.

Finally, claim 76 is another independent claim based upon claims 1 and 75 but revised to recite only the exemplary embodiments of decreasing appetite, food intake or calorie intake, as supported throughout the specification and PCT claims, such as in original claim 1.

It will therefore be understood that no new matter is encompassed by any of the amended or new claims.

VII. Sequence Listing

A corrected sequence listing is enclosed herewith for formal entry into the U.S. application. As the corrected sequence listing was submitted and explained during the international phase (copy enclosed as **Exhibit A**), further comments should not be required in the U.S. national stage. Nonetheless, the following explanation is provided.

In the PCT application as filed, there was one clerical error in each of the sequences represented by SEQ ID NOs:336, 337, 338 and 339, as given at pages 94 and 95 of the specification and in the sequence listing. In each case, an amino acid was incorrectly listed as "The" instead of "Thr". The errors were pointed out by the European Patent Office acting as the international searching authority in a communication dated June 10, 2003 (included within **Exhibit A**).

In a response dated July 07, 2003 (included within **Exhibit A**), Applicants' European representatives submitted a corrected sequence listing. The response also established that the inclusion of "The" instead of "Thr" in SEQ ID NOs:336, 337, 338 and 339 was an obvious error and that rectification by replacing the incorrect "The" with the correct "Thr" would be understood by those of ordinary skill in the art.

In particular, the response of July 07, 2003 (**Exhibit A**) established that as there is no amino acid termed "The", the presence of "The" was an obvious error and that those of ordinary skill in the art would realize that nothing else could have been intended other than what is submitted in rectification. As SEQ ID NOs:336, 337, 338 and 339 pertain to GLP-1 peptides, which were known before the priority date of the present application, and were known to contain "Thr" at the position where "The" was incorrectly given (see WO 99/47161, page 8, included within **Exhibit A**), replacing the incorrect "The" with the correct "Thr" would be clearly understood by those of ordinary skill in the art.

The listing of "The" instead of "Thr" in SEQ ID NOs:336, 337, 338 and 339 in the PCT application as filed therefore represents a clerical error that can properly be corrected by amendment in accordance with PCT Articles 19 and 34. As both the error (The instead of Thr) and the nature of the correction (changing The to Thr) would be known to the skilled person, nothing could have been intended than what is offered as correction and the amendment does not result in added subject matter.

The same corrections are also proper under U.S. statutes and case law, as the same reasoning applies. The present amendments are therefore proper, as one of ordinary skill in the art would not only recognize the existence of the error in the specification, but would also appreciate the appropriate correction. *In re Oda*, 170 USPQ 268 (CCPA 1971). See also, MPEP 2163.07, describing amendments that are NOT new matter (emphasis as in original; MPEP, February 2003, page 2100-177, column 2). Therefore, the amendments to the specification and sequence listing do not constitute new matter.

VIII. Fees and Formalities

The national filing fee and claim fees are included herewith. The fees have been calculated after the present changes to the claims. Any omitted fees should be deducted from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4040.001000. Applicants have chosen to pay large entity fees and reserve the right to request a refund.

As further precautions for the U.S. application, additional versions of the formal drawings and sequence listing are presently enclosed. The executed formal documents and any procedural requirements deemed necessary by the Office will be completed in due course.

Should the Office have any questions or comments, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,
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